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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/244,792	02/05/1999	ALDO T. IACONO	P32130	4164

21003 7590 05/23/2005

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/244,792	IACONO, ALDO T.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 20, 2004 has been entered.

Claim Rejections 35 U.S.C. 112

a. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 19-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "non-encapsulated cyclosporine" lack support from the application as originally filed. It is recognized the application disclose the genius (cyclosporine in general) and particular species of non-encapsulated cyclosporine (the examples). However, the application lacks a proper written description for the subgenus "non-encapsulated cyclosporine." New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., In re Lukach, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); In re Smith, 458 F.2d 1389, 1395, 173 USPQ 679,

683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). See MPEP 2163.

Claim Rejections 35 U.S.C. 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 38, 40, 41, 43, 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Aldo et al. (IDS).

5. Aldo et al. teaches a cyclosporin composition for aerosol delivery consisting of cyclosporin, a solvent and a propellant and the method of using the same for treating lung graft rejections. See, the whole article, particularly, page 1691, col. 2, the paragraph subtitled "Drug preparation, aerosol generation, and therapy." The composition has a concentration of about 60 mg/ml, therefore would meet the limitation of effective dose herein claimed.

Claim Rejections 35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 19-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adjei et al. (US 5,635,161), Waldrep et al. (US 5,958,378), in view of Knight et al.(5,049,388), Gordon et al. (US 6,~~657~~572,893) and Aldo et al. (Am J, Respir. Crit. Care Med. Vol. 155, pp 1690-1698, 1997, IDS)

8. Waldrep et al. and Adjei et al. teaches that cyclosporins are old and well known I combination with various pharmaceutical carriers and excipients in various dosage forms, particularly, aerosol dosage form, wherein the particles size (MMAD) is about 1 to 2 μm . These medicaments are taught as useful for treating graft rejections, inflammation and those conditions herein claimed and disclosed. Specific liposome aerosol dosages are disclosed. See, particularly, the abstract, col. 4, line 22 to col. 5, 64, the examples, col. 13, lines 3-60, and the claims in Waldrep et al. and Col. 1, lines 15-35, and the examples. in Adjei et al. Note, in liposome, the drug is homogeneously distributed among the carrier. Therefore, the carrier, whether be solid (Waldrep et al.) or liquid (Adjei et al.), is considered to be a solvent for the drug. Further, the liposome would not considered as encapsulated since the cyclosporine is homogenously distributed within the carrier, not encapsulated by the carrier.

9. Waldrep et al. and Adjei et al. do not teach expressly the various unencapsulated dosage form, or the dosage levels herein claimed, or the particular time as herein claimed.

10. However, Knight et al. teaches that cyclosporins aerosol dosage may be in the form of powder. See, particularly, example 2 therein. Gordon et al. disclosed that dry powder is a well-known form for pulmonary aerosol drug delivery. See, particularly, col. 1, lines 15-67, and the claims. Aldo et al. teaches a cyclosporin composition for aerosol delivery consisting of cyclosporin, a solvent and a propellant and the method of using the same for treating lung graft

rejections. See, the whole article, particularly, page 1691, col. 2, the paragraph subtitled "Drug preparation, aerosol generation, and therapy."

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to treating the patients of organ transplantation within 10 day after the transplantation or prior to the development of symptoms associated the transplant rejection with the aerosol cyclosporins composition herein, or treating other patients who would benefit from the administration of cyclosporins with the aerosol composition herein.

A person of ordinary skill in the art would have been motivated to treating the patients of organ transplantation within 10 day after the transplantation or prior to the development of symptoms associated the transplant rejection with the aerosol cyclosporins composition herein, or treating other patients who would benefit from the administration of cyclosporins with the aerosol composition herein because cyclosporins are known to be useful for organ transplantation patients and are known for treating inflammatory disease herein, and are particularly known to be delivered through pulmonary delivery. Further, the cited prior art as a whole teach various aerosol formulation of cyclosporins, encapsulated, or un-encapsulated as an improvement over simple aerosol employment of powdered active ingredient, and the aerosol cyclosporin as useful for an anti-inflammation, anti-rejection medicaments. The skilled artisan would have possessed all conventional administration regimens, and seen the selection of one or another as the simple selection from among obvious alternatives. Further, optimization of a result effective parameter, e.g., effective amount of a therapeutical agent, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. Further, as disclosed in the prior art, the employment of the particular method disclosed therein is to improve the old and

well-known aerosol delivery method. Therefore, employ the compound only without the further employment of carrier as herein recited would have been within the purview of the skilled artisan.

Response to the Arguments

11. Applicants' remarks and the declaration filed under 1.132 by Aldo Iacono submitted January 20, 2004 have been fully considered, but are not persuasive in view of the new ground rejection. The arguments are moot in view the fact that non-liposome composition as disclosed by Alto e tal. and Gorden et al. are known in the art and have been shown to be a effective in pulmonary delivery. Particularly, the examples disclosed in the cited prior art, e.g., liposome, are not encapsulated cyclosporins (i.e., particles with cyclosporins inside and a coating outside), but a solution. Further, Gordon et al. disclosed that dry powder is a well-known form for pulmonary aerosol drug delivery. See, particularly, col. 1, lines 15-67, and the claims. Aldo et al. teaches a cyclosporin composition for aerosol delivery consisting of cyclosporins, a solvent and a propellant and the method of using the same for treating lung graft rejections. See, the whole article, particularly, page 1691, col. 2, the paragraph subtitled "Drug preparation, aerosol generation, and therapy." Therefore, unencapsulated cyclosporine compositions as aerosol dosages have been old and well-known in the art. It is further noted that the pending claims would read on liposome composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617